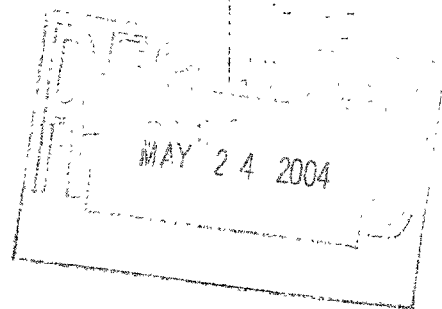




May 17, 2004

Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810),  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740



**Section 403(r)(6) Notification**

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Formula for Healthy Joints**

**Osteo Joint™ combines three complementary ingredients to help maintain healthy joints and connective tissue. The natural ingredients work together in this advanced formula to support the production of cartilage and fortify production of collagen.**

**Osteo Joint™ supports healthy, flexible joints with these three nutrients:**  
**Glucosamine Sulfate-** supplies glucosamine, a naturally occurring amino sugar which is a basic building block for producing cartilage, synovial fluid and other connective tissue. It is needed for healthy structure and function of joints for optimum mobility. As bodies age, cartilage, a spongy tissue which acts as a shock absorber in joints, may need additional nourishment to maintain adequate mobility and cushioning support.

**MSM (Methylsulfonylmethane)-** Provides nutrients that work in conjunction with Glucosamine Sulfate to provide the building blocks of collagen, an important component of healthy joints and connective tissue.

**Devil's Claw-** An herb that is native to Southern Africa, it has been popular in Europe for the past twenty years. The Devil's Claw used in Osteo Joint™ is a standardized herbal extract (to 4% hapagosides) that may assist in joint mobility.

on the following product:

**YourLife® Osteo Joint**

Very truly yours,

**Leiner Health Products**

  
\_\_\_\_\_  
William Cochran, Manager of Regulatory Affairs

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Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810),  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
(continued)

The following brands also use the above statement:

*Albertson's*  
*BI-MART*  
BIO BALANCE®  
COUNCIL LABS®  
CVS®  
ECKERD®  
*equate®*  
Hannaford®  
HealthLine  
health PRIDE  
*Kash n' Karry*  
KIRKLAND Signature™  
Kroger®  
Longs  
MARC'S  
Member's Mark  
MEIJER™

Nature's Origin®  
NATURE'S VALLEY™  
NATURITE®  
*NUTRA CHOICE*  
NUTRI-BLEND  
Oscor®  
PHARMACIST FORMULA®  
BODYCOLOGY™  
SAFEWAY SELECT™  
Sav-on™  
*Shaw's*  
*ShopKo®*  
Spring Valley®  
TARGET®  
TOP CARE®  
TRUNATURE®  
Wegmans®